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HAHN LOESER & PARKS, LLP One GOJO Plaza Suite 300 AKRON, OH 44311-1076				
EXAMINER				
BHAT, NARAYAN KAMESHWAR				
ART UNIT		PAPER NUMBER		
1634				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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akron-docket@hotmail.com

### Office Action Summary

**Application No.**

10/597,954

**Applicant(s)**

ABUDOKIRIM ET AL.

**Examiner**

NARAYAN K. BHAT

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **FINAL ACTION**

1. This action is in response to papers filed May 19, 2009. Applicant's amendments requiring macropores having a diameter in the range of about 10 nm to about 100 nm to about 10  $\mu$ m to about 100  $\mu$ m necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

### ***Claim status***

2. Claims 1-20 are pending in this application.
3. Applicants have amended claims 1, 2, 4, 8, 9, 17 and 18. Amendments to claims 1, 2, 4, 8 and 9 have been reviewed and entered.
4. Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, **without** traverse in the reply filed on September 11, 2008 and made final in the office action mailed November, 19, 2008.
5. Claims 1-16 are under prosecution.

### ***Claim Rejections - 35 USC § 112***

6. Previous rejections of claims 1-16 under 112 second paragraph have been withdrawn in view of claim amendments (Remarks, pg. 6, paragraph 2). Applicants note that the claim 4 was considered indefinite due to the recitation of a micropore size that included zero. As discussed in the previous office action, claim 3 requires that monolith structure has micropores in the macropores. A micropore size of zero nm as required in the previous claim 4, does not further define the micropore, instead indicates that

monolith structure consists of only macropores. Also, new rejections are set forth below necessitated by new claim amendments.

***First Paragraph -New matter***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Following rejection is necessitated by claim amendments.***

8. Claims 4 and dependent claims 12 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time of application was filed, had a possession of the claimed invention. MPEP 2163.06 notes, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

In the instantly rejected claims, the new limitation of "a micro-pore size of greater than zero" in claim 4 appears to represent a new matter. Applicant asserts that claim 4 does not require additional support (Remarks, pg. 6, and paragraph 1). Although support for the size of the micro-pore is found in the instant specification (e.g., paragraph 0081), support for the micro-pore having size greater than zero nm is not found. Furthermore, a review of the entire instant specification and other documents by the examiner did not find any support for the second oligonucleotide probe.

The written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement (See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads)." (MPEP § 2163).

Applicant is required to cancel the new matter in the reply to this Office Action or identify the new matter in the specification as originally filed other than the citations on the record. Since no support for the second oligonucleotide has been identified, the claims are rejected as incorporating new matter.

### ***112 Second Paragraph***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. Claim 1 recites the limitation "the micro-pores" in line 7. There is insufficient antecedent basis for "the micro-pores" in the claim, which previously defines macro-pore. It is suggested that the claim be provided proper antecedent basis.

12. Claims 2-16 are indefinite because they are dependent from claim 1.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-3, 5-7 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38).

***Previous rejections are maintained. Additional limitations of amended claims taught by Tennikova et al are also addressed below.***

Regarding claim 1, Tennikova et al teaches an apparatus for separating and purifying nucleic acids comprising an integral monolith structure (i.e., monolithic continuous structures), wherein macro-pores continuously extending from one end of the monolith structure to the other end and corresponding to the sizes of nucleic acids are provided and configured so that nucleic acids corresponding to the macro-pores can be retained respectively by allowing a solution containing nucleic acids to be separated to pass there through (Fig. 4, right panel, Fig. 7, and Abstract, pg. 29, column 2, paragraph 3, pg. 32, column 2, paragraph 2). Tennikova et al also teaches that the average macropore size, (i.e., diameter) is about 0.5  $\mu\text{m}$  (Fig. 3b and pg. 32, column 2, paragraph 1, line 6). The diameter of the macropore of about 500 nm is in the range of about 100 nm to about 1  $\mu\text{m}$  as claimed.

Regarding claim 2, Tennikova et al teaches that the monolith structure employs silica (pg. 33, section 4.1) or a hybrid material containing an organic material and silica (Fig. 3b and pg. 33, section 4.1).

Regarding claim 3 and 7, Tennikova et al teaches that the porous body of the monolith structure has micro pores (i.e., small globules) in the macro pores (Fig. 3b and pg. 29, column 1, paragraph 1).

Regarding claim 5 and 10-12, Tennikova et al teaches disc formed by monolith structure and further teaches disc is placed in a column tube to form a monolith solid phase column (Fig. 2, pg. 28, column 1, paragraph 2, column 2 and paragraph 3)

Regarding claims 6 and 13-16, Tennikova et al teaches disc formed by monolith structure (Fig. 2, pg. 28, column 1, paragraph 2) and further teaches monolith solid phase column formed by detachably attaching a base formed with the monolith structure to a cylindrical body having the top and the bottom opened (Fig. 2, See the CIM monolith disks and dedicated cartridge with open end and pg. 28, column 2, paragraph 2, lines 1-3).

15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hatch (USPN 6,238,565 issued May 29, 2001).

Regarding claim 1, Hatch teaches an apparatus for separating and purifying nucleic acids comprising an integral monolith structure (i.e., monolithic continuous structures), wherein macro-pores continuously extending from one end of the monolith structure to the other end and corresponding to the sizes of nucleic acids are provided

and configured so that nucleic acids corresponding to the macro-pores can be retained respectively by allowing a solution containing nucleic acids to be separated to pass there through (column 8, lines 1-19). Hatch also teaches that the pore size (i.e., diameter) of about 10 nm to about 5000 nm (column 8, lines 1-3), which is in the range of diameter of about 10 nm to about 100 nm, or about 100 nm to about 1 micrometer or about 1 micrometer to about 10 um.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



18. Claims 1- 4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38) in view of Urthaler et al (USPGPUBNO. 2004/0002081 filed, Dec. 18, 2002).

Claim 4 is dependent from claim 3, which is dependent from claim 2, which is dependent from claim 1. Claim 9 is dependent from claim 2. Claim 8 is dependent from claim 1. Teachings of Tennikova et al regarding claims 1-3 are described above in section 14.

Regarding claims 4, 8 and 9, Tennikova et al teaches porous body of the monolith structure has macro pores size (i.e., diameter) of 0.5  $\mu\text{m}$  (Fig. 3b and pg. 32, column 2, paragraph 1, lines 5-6) and further teaches monolith structure has microglobules (i.e., micropores (Fig. 3b, pg. 29, column 1, paragraph 1). Tennikova et al do not teach the micropore size of greater than zero and less than 100 nm. However, size of the micropore in monolithic structures was known in the art at the time of the claimed invention was made as taught by Urthaler et al.

Urthaler et al teaches a monolithic structure comprising macro and micro pores and further teaches that the size of the micropore (i.e., mesopore) is about 13 nm, which is greater than zero and less than 100 nm as claimed (paragraphs 0028 and 0029). Urthaler also teaches that the monolith structures comprising micro pores of nanometer size pores have a higher flow rates and is better for transport and separation of macromolecules (paragraph 0028 and 0029).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the size of the micropore monolith

structure of Tennikova et al with the micropore of nanometer size of Urthaler et al with a reasonable expectation of success.

An artisan having the ordinary skill in the art would be motivated to modify the size of the micropore monolith structure of Tennikova et al with the expected benefit of having monolith structures comprising nanometer size pores having a higher flow rates and better for transporting and separating macromolecules as taught by Urthaler et al (paragraph 0028 and 0029).

19. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch (USPN 6,238,565 issued May 29, 2001) in view of Tennikova et al (J. High Resol. Chromatogr., 2000, 23, 27-38) and further in view of Urthaler et al (USPGPUBNO. 2004/0002081 filed, Dec. 18, 2002).

Teachings of Hatch regarding claim 1 are described above in section 15.

Regarding claim 2, Hatch teaches that the monolith structure employs an organic monolith structure on a glass (column 9, lines 24-28). Hatch does not teach a glass or silica monolith structure.

Regarding claim 3 and 7, Hatch teaches that the porous body of the monolith structure has micro pores (i.e., small globules) in the macro pores (column 8, lines 13-17).

Regarding claims 4, 8 and 9, Hatch teaches that the porous body of the monolith structure has micro-pores (i.e., small globules) within the macro-pores (column 8, lines

13-17) and further teaches that the size of the micro-pores are about 1-2 microns (column 8, line 15).

Regarding claims 5 and 10 -12, Hatch teaches solid phase column comprising monolith structure (column 9, lines 63-65) but do not teach about disc formed with monolith structure.

Regarding claims 6 and 13-16, Hatch teaches a monolith solid phase column formed with the monolith structure to a cylindrical body having the top and the bottom opened (i.e., column with diameter and length, column 10, lines 17-19 and lines 27-28) but do not teach about forming column by detachably attaching a base formed with monolith structure. It is noted that the structural requirements recited in said claims are cylindrical body having open at both ends (i.e., open column) and monolith disc. As described above Hatch teaches the open column. However, silica monolith structure and disc formed with monolith structure were known in the art at the time of the claimed invention was made as taught by Tennikova et al.

Tennikova et al teaches that the monolith structure employs silica (pg. 33, section 4.1) or a hybrid material containing an organic material and silica (Fig. 3b and pg. 33, section 4.1). Tennikova et al also teaches that the porous body of the monolith structure has micro pores (i.e., small globules) in the macro pores (Fig. 3b and pg. 29, column 1, paragraph 1). Tennikova et al further teaches disc formed by monolith structure (Fig. 2, pg. 28, column 1, paragraph 2) and further teaches monolith solid phase column formed by detachably attaching a base formed with the monolith structure to a cylindrical body having the top and the bottom opened (Fig. 2, See the

CIM monolith disks and dedicated cartridge with open end and pg. 28, column 2, paragraph 2, lines 1-3). Tennikova et al also teaches that monolithic discs are most reliable and cheap, allow separation of macromolecules very rapidly, and are far superior to the traditionally used slow columns (pg. 32, column 1, paragraph 1, pg 37, column 2, and paragraph 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the monolith solid phase column of Hatch with disc formed with monolith structure of Tennikova et al with a reasonable expectation of success with the expected benefit of having monolithic discs, which are most reliable and cheap, allow separation of macromolecules very rapidly, and are far superior to the traditionally used slow columns as taught by Tennikova et al (pg. 32, column 1, paragraph 1, pg 37, column 2, paragraph 2).

Hatch and Tennikova et al do not teach about the micropore size of greater than zero and less than 100 nm. However, size of the micro pores in monolithic structure was known in the art at the time of the claimed invention was made as taught by Urthaler et al.

Urthaler et al teaches a monolithic structure comprising macro and micro pores and further teaches that the size of the micropore (i.e., mesopore) is about 13 nm, which is greater than zero and less than 100 nm as claimed (paragraphs 0028 and 0029). Urthaler also teaches that the monolith structures comprising micro pores of nanometer size pores have a higher flow rates and is better for transport and separation of macromolecules (paragraph 0028 and 0029).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the size of the micropore monolith structure of Hatch with the micropore of nanometer size of Urthaler et al with a reasonable expectation of success.

An artisan having the ordinary skill in the art would be motivated to modify the size of the micropore monolith structure of Hatch with the expected benefit of having monolith structures comprising nanometer size pores having a higher flow rates and better for transporting and separating macromolecules as taught by Urthaler et al (paragraph 0028 and 0029).

***Response to remarks from Applicants***

***Claim Rejections - 35 USC § 102***

20. Applicants argument with respect to claims 1-16 as being anticipated by Tennikova et al have been fully considered and are not persuasive for the following reasons.

Applicants argue that Tennikova et al do not teach purifying nucleic acids of greater lengths or suggest varying the size of the macropores to purify nucleic acids of various lengths (Remarks, pg. 7, paragraph 2). This argument is not persuasive because the claim does not require varying the size of the macropore but rather requires pores of diameter ranging from 10 nm to 100um. As described above in section 14, Tennikova et al teaches pores having a diameter of 500 nm (Fig. 3b and pg.

32, column 2, paragraph 1, line 6), which is in the range of about 100 nm to about 1  $\mu$ m as claimed. Therefore, arguments do not commensurate with the scope of the claim.

Applicants further argue that Hatch does not teach or suggest a variation in pore size according to the size of nucleic acid to be purified (Remarks, pg. 7, paragraph 3). This argument is not persuasive because Hatch teaches monolithic structure having pore diameter of 1-5 microns to separate nucleic acids of 2072 and 3147 bases (column 8, lines 1-11), which is in the claimed range of about 1 to about 5  $\mu$ m. Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitation of the claim (MPEP 2114). Since Hatch teaches the claimed monolithic structure with the claimed pore size range of about 1  $\mu$ m to about 10  $\mu$ m, the reference meets the limitation of the claim.

Applicants further argue that Hatch does not teach a monolith structure made of glass or silica or hybrid material containing an organic material and a glass or silica (Remarks, pg. 7, paragraph 4). This argument is moot because as described above in section 19, Tennikova et al teaches monolith structure made of silica or hybrid of silica and an organic material.

Applicants argue that a monolith structure made of organic polymer includes impurities and are soft and cannot be used for centrifugation (Remarks, pg. 7, paragraph 4). These arguments are not persuasive because Applicant's assertion is not supported by any evidence or support documents. Furthermore, arguments of counsel

are not found persuasive in the absence of factual showing. MPEP 716.01(c) makes clear that the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

Also, as described above and in section 19, Hatch in view of Tennikova et al teaches monolith structure of silica and organic material and therefore, unsupported arguments are not persuasive.

Applicant's argument regarding the size of the micropore in claims 3- 7 (Remarks, pg. 8, and paragraph 1) is not persuasive because as described above in section 19, claimed micropore size of less than 100 nm is taught by Urthaler et al.

***Claim Rejections - 35 USC § 103 (a)***

21. Applicants arguments regarding Teachings of Hatch in view of Urthaler and Hatch in view of Tennikova et al are directed cited art in combination not teaching changing the size of the macropores in the monolith according to the size of the nucleic acid molecule to be purified (Remarks, pg. 7, paragraphs 3 and 4). These arguments are not persuasive because claim does not require changing the size of the macropore according to the size of the nucleic acid molecule to be purified. Therefore arguments

do not commensurate with the scope of the claims. Applicants are reminded that the claimed device must be defined by structure. It is maintained that the cited references teach all the structure required by the claim.

### ***Conclusion***

22. No claims are allowed.
23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Douglas) Schultz can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634